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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,621	07/18/2003	Jan Weber	S63.2-10856-US01	2650

490 7590 12/08/2009  
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EXAMINER
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KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

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12/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/622,621	<b>Applicant(s)</b> WEBER ET AL.	
	<b>Examiner</b> CHRISTOPHER D. KOHARSKI	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08/06/2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27,28,30-38 and 63-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27,28,30-38 and 63-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Acknowledgements***

The Examiner acknowledges the reply filed 08/06/2009 in which claims 27 and 63 were amended. Currently claims 27-28, 30-38 and 63-70 are pending for examination in this application.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "first layer is an outer layer and the second layer is an inner layer" and "a guidewire extending through said lumen" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

Claims 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaffer et al. (USPN5,049,132). Shaffer et al. discloses a balloon catheter for delivering therapy agents.

Regarding claims 32-36, Shaffer et al. discloses medical dilation balloon (4, Figure 1) comprising a multi-layer (44, 16) polymeric material film comprising at least first (44) and second layers (16), each layer having an inner and an outer surface, said first and second layers being in adherent contact (via posts 50) with each other over a coextensive area along respective outer and inner surfaces, each of said first and second layers having an at-rest configuration (deflated balloon state) defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface (in that the balloon layers (16, 44) are smaller and larger than one another respectively), the at-rest configuration being when said respective outer and inner surfaces are unstressed (i.e. deflated balloon state, Figures 1-4).

***Claim Rejections - 35 USC § 102e***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 36-38, 65, and 69-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Steadham et al. (USPN7,331,933). Steadham et al. discloses a balloon with compression member.

Regarding claims 32, 36-38, 65, and 69-70, Steadham et al. discloses discloses medical dilation balloon (4, Figure 1) comprising a multi-layer (40, 30, 60, 42) polymeric material film comprising at least first (40) and second layers (30), each layer having an inner and an outer surface, said first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces, each of said first and second layers having an at-rest configuration (deflated balloon state, unstretched band) defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface (physical size differential between the layers, and pretensioned elastic bands that contract when placed upon the balloon) (col 4, ln 40-60) are smaller and larger than one another respectively), the at-rest configuration being when said respective outer and inner surfaces are unstressed (i.e. deflated balloon state, Figures 1-4).

Steadham et al. further discloses a balloon comprising a balloon body (30) having a proximal end (near 46) and a distal end (near 34), and the balloon (30)

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comprising circumferential elastic bands (40, 42) on the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration (col 4, ln 40-60, Figure 2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27-28 and 63-64 are rejected under 35 U.S.C 103(a) as being unpatentable over Anderson (USPN6,007,517) in view of Yang et al. (US2001/0003796).

Regarding claims 27-28 and 63-64, Anderson discloses a medical balloon (3, Figures 1A-1B) having a longitudinal axis (along tube 2) and proximal (near 4) and distal ends (near 3 the balloon (5) connecting to a coaxial shaft (4) at the proximal end thereof and connecting to the same (4) or a different coaxial shaft at the distal end thereof, and having a central body wall portion between each end spaced apart from the balloon

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ends and connected thereto by means of tapering proximal (ends of balloon 3) and distal wall (ends of balloon 3) portions, respectively, wherein the balloon (3) further comprises a lumen (7) offset from the longitudinal axis (along axis of tub 2) extending through the tapering proximal and distal wall portions, the lumen spaced apart from the coaxial shaft at the proximal end and the coaxial shaft at the distal end (Figures 1A-3A).

Anderson meets the claim limitations as described above except for the specific balloon materials.

However, Yang et al. teaches a hydrophilic lubricity coating.

Regarding claims 27-28 and 63-64, Yang et al. teaches a balloon catheter (10, Figure 2) wherein the balloon formed of radiation cured polymerized composition ([0053]).

At the time of the invention, it would have been obvious to incorporate the hydrogel exterior coating of Yang et al. to the system of Anderson in order to increase balloon insertion and tracking within the patient by adding a lubricous exterior coating. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Yang et al. ([0001-0010]).

### ***Claim Rejections - 35 USC § 103***

Claims 66-68 are rejected under 35 U.S.C 103(a) as being unpatentable over Steadham et al. (USPN7,331,933) in view of Crocker et al. (USPN6,120,523).

Steadham meets the claim limitations as described above except for the bands being

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located on in the interior of the balloon and the balloon comprising a radiation cured polymer composition.

However, Crocker et al. teaches a focalized intraluminal balloon.

Regarding claims 66-68, Crocker et al. teaches a polymeric (cross-linked polyethylene, col 7, ln 35-55) balloon and is a multi-layer polymeric film (39, 36, 38, 40, 42, 44) wherein a first (36, 48) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 2-3), with a layer comprising an elastomeric band (40, 44) that is stretched during the configuration change.

At the time of the invention, it would have been obvious to change the placement of the bands and the balloon materials of Steadham in order to gain additional balloon inflation control properties. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Crocker et al. (cols 1-2).

### ***Claim Rejections - 35 USC § 103***

Claims 30-31 are rejected under 35 U.S.C 103(a) as being unpatentable over Anderson (USPN6,007,517) in view of Yang et al. (US2001/0003796).

Anderson as modified by Yang et al. meets the claim limitations as described above except for the device being used in with a stent delivery catheter or with a rapid exchange catheter.

Regarding claims 30-31, it would have been obvious to use the medical balloon device as disclosed by Boussignac et al. in combination with a stent delivery catheter or rapid exchange catheter since it well known in the medical arts to use stents and exchange catheter to treat body arteries and maintain vessel patency after procedures.

### ***Response to Arguments***

Applicant's arguments filed 08/06/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Shaffer et al. (USPN5,049,132) reference does not disclose "...a first and second layer being in adherent contact with each other over a coextensive area along respective inner and outer surfaces...", and that Steadham et al. (USPN7,331,933) does not disclose "...circumferential elastic bands...the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface...".

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Regarding the Shaffer et al. (USPN5,049,132) reference, the Examiner asserts the claim scope only requires the layers to be "in adherent contact" or connected, coupled or attached to each other. The first and second layers (44 and 16) are connected to each other via the posts (50) and are adhered to each other by these posts along the length of the layers. The Examiner does not consider the claim scope to cover layers that each have an inner and outer surface directly bonded to each other over the entire length thereof.

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Regarding the Steadham et al. (USPN7,331,933), the Examiner asserts that the at rest surface area (band placed on balloon in contracted state) of the first layer (40) is smaller than the at rest surface area of the second layer (30) (balloon in deflated state) because of the compression applied to the balloon surface presented by the compression of the applied bands, (see Figure 2) this is evidenced by the uniform outer surfaces created when the bands are placed on the balloon (30) for attachment (col 4, ln 50-67). The Steadham et al. reference also reference this teaching as shown by the difference in diameters of the balloon skirt sections which are influenced by the compression of the balloons bands (40, 42).

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure, see PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. KOHARSKI whose telephone number is (571)272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 12/03/2009

/Christopher D Koharski/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763